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510(K) Summary

NOV 2 1 2006

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, and the relevant 510(K) submission guidance.

The assigned 510(K) number is:

1. **Submitter's Identifications:**
   Mr. Mok Chi Wing
   Choice Smart Health Care Company Limited.
   RM 1901, CC WU BUILDING,
   302 HENNESSY ROAD,
   WANCHAI
   Hong Kong

   Date Summary Prepared: April 25, 2006

2. **Name of the device:**
   Trade name: Infrared Ear Thermometer (IRT-21 and IRT-22)
   Common Name: Clinical Electronic Thermometer
   Classification Name: Thermometer, Electronic, Clinical

3. **Information of the 510(K) Cleared Device(Predicate Device):**
   Infrared Ear Thermometer (GT-302) (K010383).

4. **Device Description:**
   Infrared Ear Thermometer (IRT-21 and IRT-22) is used to measure body temperature from ear canal. Operation is based on measuring the natural thermal radiation emitted from the tympanic membrane and adjacent surfaces. Probe cover is used for measuring to ensure accurate temperature measurement. For hygienic purpose, it is advised to discard the probe cover after each use.
   Press the ON/OFF button to turn on the power, the symbol 88.8 appears immediately. Insert the probe into the ear canal then press the SCAN button to measure the temperature, when you hear a beep sound, the measurement is complete. The temperature is graduated on 0.1°F or 0.1°C, reading a range of 89.6°F-109.2°F(32°C-42.9°C). The ambient temperature environment is intended for used is 50°F-104°F (10°C-40°C).

5. **Intended Use:**
   Infrared Ear Thermometer (IRT-21 and IRT-22), designed with infrared technology, is used to measure body temperature from ear canal. Press the ON/OFF button to turn on the power, the symbol 88.8 appears immediately.

Insert the probe into the ear canal then press the SCAN button to measure the temperature, when you hear a beep sound, the measurement is complete. Infrared Ear Thermometer (IRT-21 and IRT-22) is intended for household and hospital use on people of all ages.

6. **Comparison to the 510(K) Cleared Device(Predicate Device):**
Infrared Ear Thermometer (IRT-21 and IRT-22) has the same intended use and technological characteristics as the cleared device of Infrared Ear Thermometer (GT-302) (K010383). Although Infrared Ear Thermometer (IRT-21 and IRT-22) has slightly broader ambient operating temperature, slightly broader display temperature range and more memorization capacity compared with legally marketed one, these differences do not affect the safety, performance of the subject device. So the new device is substantial equivalence to the selected predicate device.

7. **Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:**
Various testing was performed as per ASTM E1965-1998 (Re-approved 2003) and ASTM E1104-1998 (Re-approved 2003). Accuracy testing was done at 35℃/95℉, 37℃/98.6℉, 41℃/105.8℉ according to the requirements of ASTM E1965-98 (Re-approved 2003) and results show that no individual reading was in error by more than the acceptable maximum error. Declaration of conformity letter of conformed standards sees Appendix VIII.

Electrical safety conforms to applicable voluntary standards IEC 60601-1, IEC 60601-1-2. And Biocompatibility conforms to applicable voluntary standards ISO 10993-1:2003 biocompatibility testing on skin irritation, in vitro cytotoxicity and sensitivity.

For predicate device (K010383), it is complied with voluntary standards includes ASTM 1965-98, ASTM 1104, IEC 60601-1 and IEC 60601-1-2 based on its 510K summary.

So the new device is substantial equivalence to the selected predicate device.

8. **Discussion of Clinical Study:**
A comparison study and clinical repeatability testing was performed between Infrared thermometer and reference thermometer. 100 patients were enrolled for this trial. The repeatability result can be considered reasonably small and will not pose a problem for diagnostic purposes. The results of clinical bias and

uncertainty indicate that this IR thermometer can be used reliably. Clinical result conform ASTM E1965-98 (Re approved 2003).

9. **Conclusions:**

Infrared Ear Thermometer (IRT-21 and IRT-22) has the same intended use and technological characteristics as the cleared device of Infrared Ear Thermometer (GT-302) (K010383). Various performance testing data which conducted according to ASTM E1965 and ASTM E1104 standards, such as accuracy test, storage test, shock test demonstrate the same safety and effectiveness as that of cleared device. In the other words, the Infrared Ear Thermometer (IRT-21 and IRT-22) is substantial equivalence to predicted device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Choice Smart Health Care Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 Northwest Lake Road
Camas, Washington 98607-9526

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Re: K063291
Trade/Device Name: Infrared Ear Thermometer (IRT-21 and IRT-22)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 11, 2006
Received: November 1, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

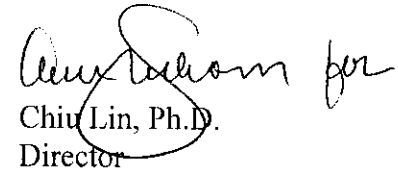
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use

510(k) Number (if known):

Device name: Infrared Ear Thermometer (IRT-21 and IRT-22)

Indications for Use:

Infrared Ear Thermometer (IRT-21 and IRT-22), designed with infrared technology, is used to measure body temperature from ear canal. Press the ON/OFF button to turn on the power, insert the probe into the ear canal then press the SCAN button to measure the temperature, when you hear a beep sound, the measurement is complete. Infrared Ear Thermometer (IRT-21 and IRT-22) is intended for household and hospital use on people of all ages.

Prescription Use _____		Over-The-Counter Use ___√___
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/21/06

...n Sign-Off)
...n of Anesthesiology, General Hospital,
...tion Control, Dental Devices
...Number: K063291